



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

AUG 20 2010

Re: EFFIENT  
Docket No.: FDA-2010-E-0048

The Honorable David J. Kappos  
Undersecretary of Commerce for Intellectual Property  
Director of the United States Patent and Trademark Office  
Mail Stop Hatch-Waxman PTE  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 5,288,726, filed by Daiichi Sankyo Company LTD., and UBE Industries, LTD., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for EFFIENT (Prasugrel Hydrochloride), the human drug product claimed by the patent.

The total length of the regulatory review period for EFFIENT (Prasugrel Hydrochloride) is 2,795 days. Of this time, 2,232 days occurred during the testing phase and 563 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: November 16, 2001.

FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 16, 2001.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 26, 2007.

FDA has verified the applicant's claim that the new drug application (NDA) for EFFIENT (NDA 22-307) was submitted on December 26, 2007.

3. The date the application was approved: July 10, 2009.

FDA has verified the applicant's claim that NDA 22-307 was approved on July 10, 2009.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,



Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

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